3M™ Attest™ 1292-S Biological Indicator for Steam
3M™ Attest™ Auto-readers

Product Profile

For Industrial Applications

Industrial Sterilization Specialties
INTERNATIONAL

3M

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Introduction

The 3M™ Attest™ 1292-S Rapid Readout Biological Indicator for Steam is a fast (3 hour readout), reliable, and convenient biological indicator for validating and monitoring steam sterilization processes when used in conjunction with the 3M Attest 293 or 290 Auto-readers. The Attest 1292-S may be used as a component of the quality system for a steam sterilization process that ensures that medical devices or pharmaceutical products are processed per the manufacturer's specifications and comply with the requirements of national and international sterilization standards. The self-contained design of the Attest 1292-S reduces testing time and eliminates the potential for cross-contamination associated with the culturing of conventional spore strips. The fluorescent readout can provide confirmation of an acceptable cycle after only 3 hours of incubation.

The Attest 1292-S provides fast, reliable results that allow the potential for inventory optimization with the assurance of using a biological indicator system for validating and monitoring the sterilization process.

The Attest 1292-S has been validated as an effective biological monitor for 132ºC (270ºF) vacuum-assisted and 121ºC (250ºF) gravity steam sterilization processes under specific test conditions. The Attest 1292-S could also be used to monitor other industrial steam sterilization processes, such as 134ºC (273ºF), with appropriate testing and validation by the end user. The suitability of the Attest 1292-S for monitoring any industrial steam sterilization process must be verified and documented by the end user.

Product Descriptions

3M™ Attest™ 1292-S Rapid Readout Biological Indicator for Steam

3M Attest 1292-S

The Attest 1292-S is a self-contained biological indicator designed for validation and routine monitoring of industrial steam sterilization processes, when used in conjunction with the 3M Attest Model 293 or Model 290 Auto-readers. The Attest 1292-S is comprised of a paper carrier inoculated with a standardized population of *Geobacillus stearothermophilus* ATCC® 7953 spores, a non-woven spore strip support, a glass ampoule containing recovery media which includes a pH indicator and a fluorogenic indicator, a plastic cap with filter, and a plastic sleeve (See Figure 1). The biological indicator has a chemical process indicator on the label that will change from rose to brown upon exposure to the steam sterilization process.

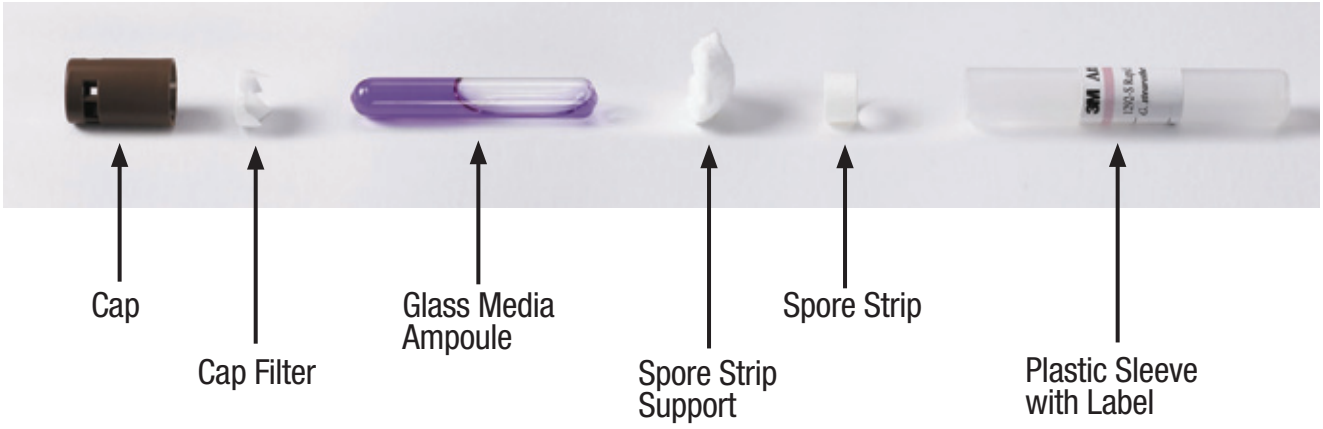

Figure 1 - 3M Attest 1292-S Components

The recovery media will produce a fluorescent response detected by the auto-reader if active alpha-glucosidase enzyme is present, and a pH color change from purple to yellow if continued incubation results in outgrowth of the test organisms (Figure 2).

Figure 2 – pH Color Change – Negative & Positive Attest 1292-S

The Attest 1292-S has been validated with a fluorescent Reduced Incubation Time (RIT) of 3 hours when used in the Model 293 or 290 Auto-reader, under specific test conditions. If desired (e.g. for validation of the 3 hour fluorescent readout), the Attest 1292-S can be further incubated to look for a media color change (purple to yellow) verifying the test organism's outgrowth. The Attest 1292-S has been validated with a color change Reduced Incubation Time of 48 hours, under specific test conditions. The reduced incubation time for 1292-S (fluorescent and/or color change) should be validated by the end user in their system.

The Attest 1292-S is compliant with ISO 11138-1:2006[1] and ISO 11138-3:2006[2] (ANSI/AAMI/ISO 11138-1:2006[3] and ANSI/AAMI/ISO 11138-3:2006[4]). Key product design and performance specifications for the Attest 1292-S are provided in this Product Profile.

The Attest 1292-S has not been tested or validated for monitoring sterilization processes other than steam, such as ethylene oxide, dry heat, radiation, hydrogen peroxide, or other chemical or low temperature processes.

The Attest 1292-S is available in cases containing 2 boxes of 300 biological indicators (600 biological indicators per case).

3M Attest Model 293 and Model 290 Auto-readers

The 3M Attest 293 and 290 Auto-readers are designed to incubate the Attest 1292-S at 60ºC ± 2ºC and automatically read the fluorescent response of the Attest 1292-S with a final end point reading at 3 hours. The Attest 293 and 290 Auto-readers are also designed to allow for further incubation of the Attest 1292-S to look for a media color change. Since media dry-out will occur upon extended incubation in the Auto-reader (typically 2-3 days) transfer of the indicators to humidified incubators will be required to insure adequate growth media during longer incubation periods.

3M Attest Auto-Reader Model 290

3M Attest Auto-Reader Model 293

The Model 290 has the capacity to incubate and read 12 Attest 1292-S biological indicators, and the Model 293 has a capacity to incubate and read 36 Attest 1292-S BIs. Both Auto-readers take automatic fluorescent readings of each biological indicator every 15 minutes, and utilize a specially designed algorithm to assess the change in fluorescence over the incubation period. The Auto-reader will indicate a positive Attest 1292-S (red "+" light) as soon as it is read and determined to be positive, and will indicate a negative Attest 1292-S (green "–" light) after the final negative reading at 3 hours.

Other biological indicators are not compatible with the Attest Model 293 and 290 Auto-readers and cannot be used with these devices. These units are designed to be used only with the power supply modules supplied by 3M. These products are non-programmable electronic devices.

Regulatory Status

Performance requirements for biological indicators used in health care facilities and industrial applications are defined by the international consensus standard series, ISO 11138 - Sterilization of health care products – Biological indicators. The 2006 version of this ISO standard series replaced the earlier versions, and also replaced the European (EN) biological indicator standard series (EN 866 Biological systems for testing sterilizers and sterilization processes). AAMI has also adopted the ISO 11138 standard series and will replace ANSI/AAMI Sterilization of health care products – Biological indicators ST 59 and ST 19 with ANSI/AAMI/ISO 11138-1 and ANSI/AAMI/ISO 11138-3, respectively.

The Attest 1292-S meets the performance requirements specified in ISO 11138, Part 1 (general requirements) and Part 3 (requirements for biological indicators for moist heat sterilization processes).

In the United States, biological indicators used in the industrial setting to validate and monitor sterilization processes are not regulated as medical devices. However, an understanding of the regulatory status of a biological indicator relative to its use in the healthcare setting may be helpful for industrial users.

The 3M Attest 1292 Rapid Readout Biological Indicator for Steam for use in health care facilities was cleared for commercial distribution by the US FDA (United States Food and Drug Administration) under 510(k) K926364 in March, 1995. The 3M Attest 1292-S is the same product design as the 3M Attest 1292, with narrower specifications and modified packaging. The Attest 1292-S is specifically designed for use in industrial applications.

The 3M Attest 290 Auto-reader was also cleared by the US FDA under 510(k) K004009 in March, 2002. It may be used to incubate and read the 3M Attest 1292-S.

The 3M Attest 293 Auto-reader was cleared by the US FDA under 510(k) K052128 in August, 2005. It may be used to incubate and read the 3M Attest 1292-S.

Attest 1292-S Rapid Readout Technology

Attest 1292-S Technology

The Attest 1292-S contains a standardized, viable population of *Geobacillus stearothermophilus* ATCC 7953 spores complying with the test organism, population, and resistance requirements described in ISO 11138:2006, Parts 1 and 3, and ANSI/AAMI/ISO 11138:2006, Parts 1 and 3. The Attest 1292-S indicates a sub-lethal steam sterilization process by providing a positive fluorescent readout (via the Attest 293 or 290 Auto-reader) after a maximum of 3 hours of incubation. The Attest 1292-S also has the capability of providing a pH-based media color change readout based on outgrowth of the acid-producing test organisms with continued incubation (48 hours, or time validated by the end user).

The fluorescent readout of the Attest 1292-S is based on the activity of an enzyme, alpha-glucosidase, produced by the *Geobacillus stearothermophilus* test organisms. The enzyme is located in the spore coat, a location typical for enzymes required for the spore activation and germination processes. The enzyme is also present in vegetative cells.[5]

In the Attest 1292-S, the alpha-glucosidase enzyme acts upon a fluorogenic substrate, 4-methylumbelliferyl-alpha-D-glucopyranoside (alpha-MUG), which is present in the biological indicator's recovery media. The enzyme hydrolyzes an alpha-glucosidic linkage, producing glucose and a fluorescent by-product, 4-methylumbelliferone (4-MU). (See Figure 3). To facilitate detection, the 4-MU is concentrated in a specific area of the Attest 1292-S spore strip by the non-woven spore strip support. The amount of 4-MU and the decision of a positive (red "+" light) or negative (green "-" light) biological indicator result is determined by the detection instrumentation and algorithm programming in the Auto-reader. (See the Auto-reader Technology section for more detail).

In a lethal steam sterilization process, the alpha-glucosidase enzyme is inactivated, and the spores are not capable of germination and outgrowth. Thus, no fluorescent response is detected by the auto-reader, which will indicate a negative

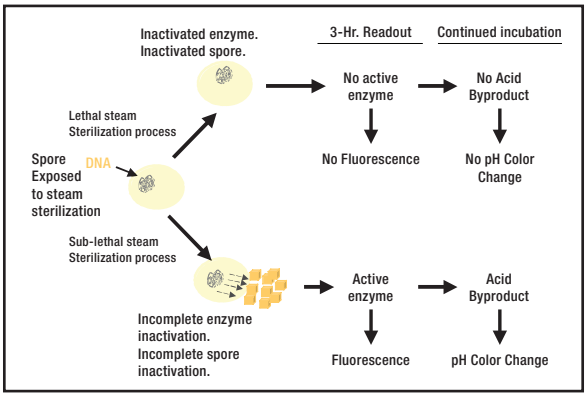

Figure 4 - Schematic of Attest 1292-S Technology

biological indicator result via a green "-" light. If the Attest 1292-S is incubated further, no pH-based media color change will occur, and the growth media will remain purple. In a sub-lethal steam sterilization process, active alpha-glucosidase enzyme will produce a fluorescent response that will be detected by the auto-reader within 3 hours of incubation, resulting in a red "+" light, indicating a positive biological indicator. If continued incubation of the Attest 1292-S results in outgrowth of the test organisms, the pH-based media color change from purple to yellow will occur. The fluorescent response is due to activity from both pre-existing (spore coat) enzyme, and enzyme synthesized *de novo* during the germination and outgrowth process.[6] A schematic of the Attest 1292-S technology is provided in Figure 4.

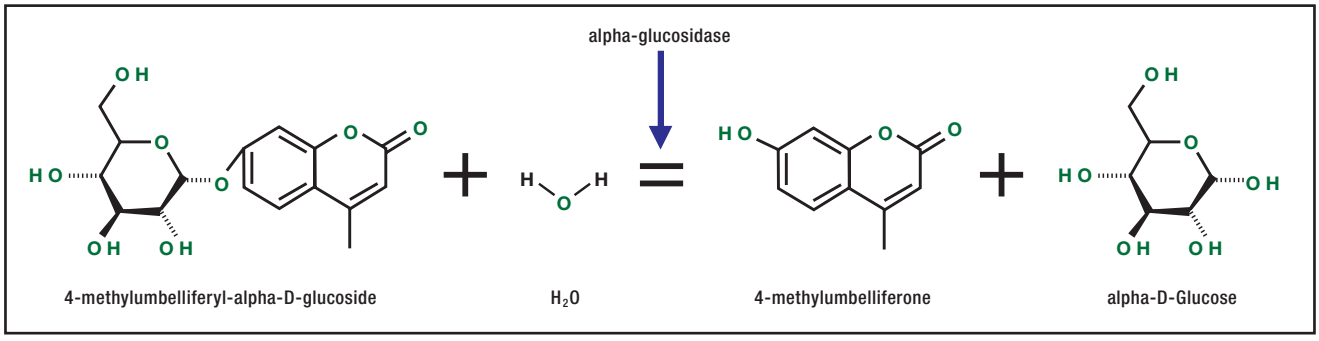

Figure 3- Attest 1292-S Fluorogenic Substrate Reaction

For Attest 1292-S, the fluorescent readout closely parallels the spore outgrowth-based pH color change readout typically used in validating and monitoring steam sterilization processes. Since the alpha-glucosidase enzyme is located in the spore coat, which is typical for enzymes involved with activation and germination, this enzyme is an excellent indicator of spore viability. In marginal sterilization conditions, there can be situations where the alpha-glucosidase enzyme is not completely inactivated, but enough spore damage has occurred such that outgrowth of vegetative cells does not occur. In these cases, it is possible to observe a fluorescent response (positive Auto-reader response) without evidence of spore outgrowth (negative pH color change response). The typical response of the 3-hour fluorescent readout and the pH color change readout of the Attest 1292-S in fractional exposure conditions is illustrated in Figure 5. This figure demonstrates that the Attest 1292-S will typically have positive fluorescent responses over a slightly greater length of exposure times than they will produce positive pH color change responses. The exact timing of the fractional windows will depend upon the specific process conditions.

The relationship between the fluorescent response and the pH-color change response has been studied extensively for both health care[7,8,9,10,11] and industrial[12] applications. In all cases, researchers found excellent correlation between the fluorescent and pH color change readouts in marginal cycles.

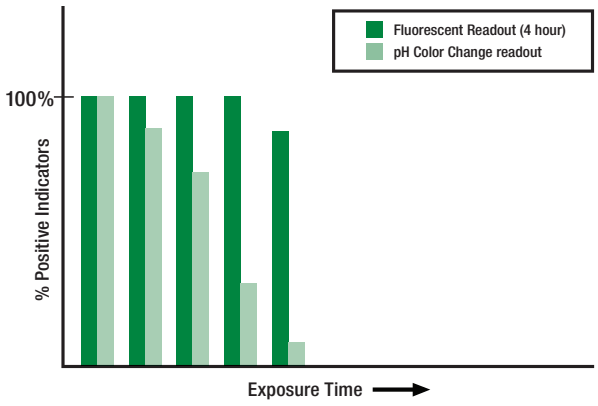

Figure 5 - Typical Attest 1292-S response in fractional exposures

Attest Auto-reader Technology

The Models 293 and 290 serve two purposes. First, they can serve as incubators for the time period required to obtain either a rapid (i.e., fluorescent) readout or to observe a colorimetric change. A maximum of twelve (Model 290) or thirty-six (Model 293) Attest 1292-S biological indicators may be incubated simultaneously. Second, the devices determine whether a potential sterilization cycle failure may have occurred by measuring the intensity of fluorescence of the media inside the Attest 1292-S. The components and operational characteristics used to accomplish these two tasks are described in the following paragraphs.

Incubation is performed by crushing the glass ampoules of the Attest 1292-S biological indicators in the “crusher well”, tapping the indicators to ensure that the media wets the strip, and placing Attest 1292-S into any of the wells provided in the aluminum incubator block. The incubator block is warmed by a heater blanket that runs the length of its front side. A thermo-electric sensor (thermistor) is placed at the middle of the incubator block and provides input to the NMOM Mother Board. The NMOM Mother Board contains a chip with embedded system software that monitors and controls incubation temperature as well as issues error codes to the digital display, when appropriate.

The second function of the Model 293 or 290 Auto-reader is to obtain a rapid readout based upon the fluorescence in the Attest 1292-S media. The measurement of fluorescence is initiated by placement of an Attest 1292-S into any of the incubation wells. Detection of insertion or withdrawal of the biological indicator is accomplished using reflective photo-electric sensors. There is one sensor for each well. Fluorescence is measured using movable subassemblies called “optical sleds”. These sleds sit on rails and can be positioned in front of each of the wells (each sled services 12 wells) by a stepper motor which is software controlled. Each sled contains a cold cathode UV fluorescent lamp (i.e., bulb) and a circuit board that monitors both the excitation intensity of

the bulb and fluorescent emissions from the Attest 1292-S. When an Attest 1292-S is initially placed into a well, that well's proximity sensor will detect the indicator's presence. A yellow light on the front panel will be illuminated indicating that incubation has begun. The stepper motor is also activated and a read sequence is initiated. When the sled moves in front of an Attest 1292-S, an initial "baseline" reading will be taken. These individual values, as well as all subsequent readings from the biological indicator, are stored in memory on the NMOM Mother Board. Twelve readings are taken (one every 15 minutes), up to the 3-hour final readout. Each time an individual Attest 1292-S biological indicator's fluorescence intensity reading is obtained, the difference in intensity from its previous reading is calculated. These differences are summed. If, after the initial four readings, or subsequent readings, the sum of the differences meets, or exceeds the threshold value in A/D (relative fluorescence) units, the biological indicator is considered positive. A positive reading is interpreted as an indication of an inadequate sterilization cycle. The positive finding is indicated to the user by a red "+" light on the front panel as well as an audible alarm. The alarm may be muted by the operator when a positive result is obtained. Pressing the mute button disables the alarm only for that specific biological indicator which was just identified as positive. Should another Attest 1292-S biological indicator turn positive, the alarm will again sound. Negative results are identified by a green "-" light on the front panel but will only appear after 3 hours of incubation if the fluorescent threshold has not been exceeded. A schematic of the Auto-reader's electro-optics system is provided in Figure 6.

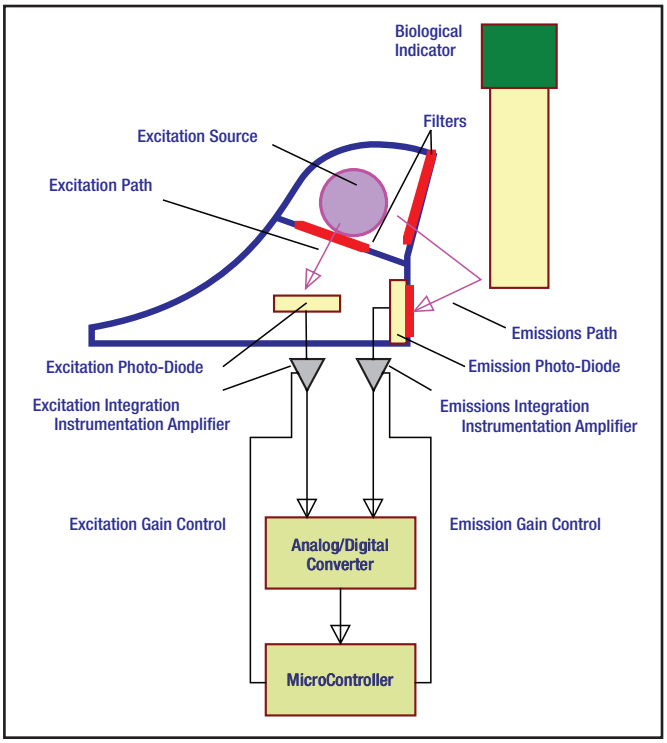

Figure 6- Auto-reader Electro-Optics Measurement Apparatus

Product Specification and Performance Information

The following sections describe the key performance specifications of the Attest 1292-S system, in some cases comparing them to the biological indicator requirements described in "ISO 11138-3:2006 Sterilization of health care products – Biological indicators for moist heat sterilization processes".

Population Specification	
3M Attest 1292-S	$1.0 \times 10^6 – 9.9 \times 10^6$ cfu/strip
ISO 11138-3:2006 – Moist heat biological indicators	1.0×10^5 cfu/strip minimum

Table 1- Population

Method: The method used for determination of viable population of the Attest 1292-S involves maceration of multiple strips to separate the spores from the paper carrier, followed by serial dilutions, plating, colony counting, and dilution calculations to determine the population. Population test results are very dependent upon the methodology used to determine those results. The test method used to confirm the population of any lot of Attest 1292-S must be identical to the method used by 3M to determine the population stated on the certification. The 3M method is described in ***3M Technical Bulletin 05-000008, 3M Attest 1292-S – Population Test Procedure***, available upon request (In the U.S., call the 3M Sterilization Technical Helpline at 1-800-441-1922, Option 2 or through your local 3M office).

Rationale: The population range for Attest 1292-S biological indicators will be over the range of 10^6 (6 logs) cfu/strip. This population range is higher than that specified for moist heat biological indicators in ISO 11138-3 (10^5 cfu/strip minimum). The higher population for Attest 1292-S is required to optimize the rapid readout feature of the product, and also provide a 6 log challenge. The intent of the narrower specification range (population maximum) is to provide a less variable indicator.

D-value Specification	
3M Attest 1292-S	1.5 – 2.5 minutes
ISO 11138-3:2006 – Moist heat biological indicators	1.5 minutes minimum

Table 2 - D-value

Method: The D-value for Attest 1292-S is determined using a Fraction Negative methodology. The D-value is determined using the pH color change (outgrowth) response of the Attest 1292-S. All exposures are completed at 121ºC (250ºF).

The test method used to confirm the D-value of any lot of Attest 1292-S must be identical to the method used by 3M to determine the D-value stated on the certification. The specific 3M method is described in ***3M Technical Bulletin 05-000006, 3M Attest 1292-S D-value Test Method***, available upon request (In the U.S., call the 3M Sterilization Technical Helpline at 800-441-1922, Option 2 or through your local 3M office).

Rationale: The D-value specification for Attest 1292-S is narrower than the range specified in for moist heat biological indicators in ISO 11138-3:2006. The intent of this specification is to provide a less variable indicator.

z-Value

The z-value specification for Attest 1292-S is based on the requirement specified in ISO 11138-3:2006. The specification for Attest 1292-S:

z-Value: ≥ 6ºC

Survival and Kill

The survival and kill values of the Attest 1292-S are based on the calculations specified in ISO 11138-1:2006. The formulas are:

Survival Time = ($\log_{10}$ population – 2) x D-value

Kill Time = ($\log_{10}$ population + 4) x D-value

These tests are conducted in a resistometer at 121ºC (250ºF). The actual calculated test times for each lot are reported on the Quality Certificate that accompanies each lot.

Fluorescent and pH Color Change (outgrowth) Survival and Kill Responses

The pH color change readout for the Attest 1292-S, based on outgrowth of the test organisms, complies with the calculated survival and kill times specified on the Quality Certificate. The fluorescent response will present a more resistant readout because of the possibility of enzyme activity without outgrowth (discussed in this Product Profile). Thus, the fluorescent readout will meet the same calculated survival time used for the color change outgrowth based readout. This insures that the Attest 1292-S biological indicators have an adequate minimum resistance. The time required to eliminate the fluorescent response may be slightly longer than the calculated kill time for the color change (outgrowth) response.

Fluorescent End Point

The fluorescent end point reported on the Quality Certificate provides information on the exposure time required to eliminate the fluorescent response. This time is calculated by use of a modified version of the normal kill time calculation. The fluorescent end point is calculated by:

Fluorescent End Point = (log_{10} population + 6) x D-value

The change from a "+4" stated in ISO 11138-1:2006, to a "+6", will result in an exposure time lengthened by time equivalent to two D-values. This additional exposure will compensate for situations related enzyme activity without outgrowth.

The Attest 1292-S has been validated with a fluorescent Reduced Incubation Time (RIT) of 3 hours when used in the Model 293 or 290 Auto-reader, under specific test conditions. The Attest 1292-S has been validated with a pH color change Reduced Incubation Time of 48 hours, under specific test conditions.

In this testing, multiple indicators are exposed to defined sterilization conditions that result in 30-80% pH color change (growth) positives after 7 days of incubation. In 3M validation and Quality Control testing, the 3-hour fluorescent readout predicts greater than 97% of the color change positives read after 7 days of incubation. The specific 3M method for verifying the 3-hour fluorescent readout is described in ***3M Technical Bulletin 05-000017, 3M Attest 1292-S 3 Hour Readout Test Procedure,*** available upon request (In the U.S., call the 3M Sterilization Technical Helpline at 800-441-1922, Option 2 or through your local 3M office).

An example of 3-hour readout data, submitted to FDA as part of the 3M Attest Model 290 Auto-reader 510k, is provided in Table 3. In this table, the fluorescent readout is the percentage of 7-day positives correctly predicted at the reduced incubation time (3 hours).

Lot Number	% Positive Indicators at 168 hours	Number of False Negative at 3 hours	3-hour Fluorescent Readout (%)
2002-05 AB	57	0	100%
2004-05 AC	73	0	100%
2002-05 AE	62	0	100%

Table 3 - Sample 3-Hour Readout Data - Attest 1292

Readout Time

The Attest 1292-S may be incubated at 60ºC ± 2ºC (140ºF ± 3ºF) beyond 3 hours to look for a pH color change response. The Attest 1292-S has been validated with a pH color change Reduced Incubation Time of 48 hours, under specific 3M test conditions.

Table 4 provides typical data comparing the 48-hour pH color change readout with the 7-day pH color change readout. In this table, the 48-hour readout is the percentage of 7-day positives correctly predicted at the reduced incubation time (48 hours).

Exposure Process	% Positive Indicators at 168 hours	Number of False Negative at 48 hours	48-hour Readout (%)
121°C Gravity	49	5	99.4%
132°C Pre-Vacuum	51	2	99.7%

Table 4 - Sample 48-Hour Readout Data - Attest 1292

The incubation time required for an appropriate prediction of the 7-day color change response should be validated by the end user in their system. For extended incubation (beyond 24-48 hours), steps such as humidified incubation will be required to prevent dry out of the growth media.

Instructions for Use

The following information is provided with the Attest 1292-S biological indicators and provides specific use instructions.

Identification and Expiration Date: Each biological indicator will be labeled with a lot code that also provides the expiration date information. The format of this code is noted below:

YYYY-MM XX

Y denotes the Year the product will expire; M denotes the Month the product will expire (last day of that month); "XX" is a 3M lot specific code. For example:

2010-03 JK

represents a product with production code JK that will expire on March 31, 2010.

The entire lot code (8 characters) must be used to describe or document the product lot. Biological indicators that are beyond their expiration date should not be used.

Inspection: Damaged biological indicators may produce erroneous results. Indicators can be damaged in shipping, or in handling (e.g. during placement into, or extraction from, a product or a process challenge device); damage by pallet handling before or after processing). Careful inspection of the biological indicator both before and after processing (before crushing the ampoule) is critical. (Note: Please follow safety precautions described in WARNING section when inspecting indicators that have been exposed to the sterilization process).

Carefully inspect each biological indicator for:

- Missing or damaged components (e.g. cap filter, spore strip, media ampoule, plastic sleeve).
- The integrity of the glass ampoule is critical. Inspect for any signs of breakage including wet spore strip, wet or dried residual media inside vial, or apparent lack of media in the ampoule.

Any damaged or suspect biological indicators should be discarded. Any results obtained from damaged biological indicators should be considered suspect.

Positive Control Tests: Positive controls (unprocessed indicators) should be tested to ensure that storage or handling has not inadvertently affected the viability of the indicator organisms or the ability of the recovery media to promote bacterial growth. Positive controls also verify that incubation conditions are appropriate.

Test at least one positive control from the same biological indicator lot for each sterilizer load monitored. Verify that the color of the chemical indicator on the biological indicator label is rose (unprocessed color). To test the positive controls, push the brown cap down onto the sleeve, sealing the top of the indicator. Crack the glass ampoule (note WARNING section below) using the crusher well on the 290 or 293 Auto-reader, and ensure that the growth media completely wets the spore strip. Gently tap the indicator on a hard surface to facilitate wetting the strip, if necessary. Immediately incubate the positive controls in a 293 or 290 Auto-reader at 60ºC ± 2ºC (140ºF ± 3ºF), with the processed indicators, for up to 3 hours. The positive control must produce a positive fluorescent response (red "+" sign) by 3 hours. Continue to incubate the positive control at 60ºC ± 2ºC (140ºF ± 3ºF) for up to 48 hours. The media color must change from purple to yellow (yellow indicates a positive biological indicator) within 48 hours. Do not continue to incubate indicators that have turned yellow (positive). Failure of the positive control tests may invalidate the processed indicator results.

Incubation and Interpretation of Processed Indicators:
WARNING: There is a glass ampoule inside the plastic vial of the biological indicator.

- Crushing or excessive handling of the biological indicator before cooling may cause the glass ampoule to burst.
- Wear safety glasses and gloves when removing the biological indicator from the sterilizer.
- Wear safety glasses when crushing the biological indicator.
- Handle the biological indicator by the cap when crushing and tapping.
- Do not use your fingers to crush the glass ampoule.

Remove the processed indicator from the sterilizer and, if applicable, its holder or PCD. Allow to cool (see WARNING section). Verify that the color of the chemical indicator on the biological indicator label has changed from rose (unprocessed color) to brown (processed color). Carefully inspect the biological indicator for any sign of damage, including a wet spore strip, dried or residual media, or lack of media in the vial. Discard any damaged indicators. To test the processed indicator, push the brown cap down onto the sleeve, sealing the top of the indicator. Crack the glass ampoule (see WARNING section) using the crusher well on the 293 or 290 Auto-reader, and ensure that the growth media completely wets the spore strip. Gently tap the indicator on a hard surface to facilitate wetting the strip, if necessary. Immediately incubate the processed indicators in a Model 293 or 290 Auto-reader at 60ºC ± 2ºC (140ºF ± 3ºF), for up to 3 hours. A green "-" readout on the Auto-reader indicates a negative biological indicator response; a red "+" readout indicates a positive biological indicator response. If desired, the user may continue to incubate the indicator at 60ºC ± 2ºC (140ºF ± 3ºF) to look for a media color change from purple to yellow at 48 hours, or an incubation time validated by the end user. Yellow media after incubation also indicates a positive biological indicator. Do not continue to incubate indicators that have turned positive.

Product Handling Information

Storage: Store Attest 1292-S biological indicators between 15-30ºC (59-86ºF) and 35% - 60% relative humidity (RH). Do not store near sterilants or other chemicals.

Disposal: Dispose of biological indicators per your facility procedure. You may wish to autoclave biological indicators at 121ºC/250ºF for at least 30 minutes.

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